**University of Michigan**

**Consent To Be Part Of A Research Study**

**1. Key Information About the RESEARCHERS and This Study**

***Refer to the blue box version of the consent template for additional instructions and required language.***

**THIS INFORMED CONSENT TEMPLATE IS THE ‘OUTLINE’ VERSION, WHICH DOES NOT CONTAIN ALL INSTRUCTIONS AND REQUIRED LANGUAGE. IRBMED’S RECOMMENDATION IS TO USE THE ‘WORKING’ VERSION AS THE TEMPLATE FOR CREATIING THE CONSENT DOCUMENT.**

**IF USING THIS OUTLINE VERSION TO CREATE THE CONSENT DOCUMENT, ALWAYS USE THE BLUE-BOX WORKING VERSION AS A COMPANION DOCUMENT FOR ADDITIONAL INSTRUCTIONS AND REQUIRED LANGUAGE.**

**DELETE ALL TEXT BOXES WITHIN THIS DOCUMENT BY SIMPLY CLICKING ON THE BORDER OF THE BOX AND HITTING DELETE.**

**Study title:**

**Company or agency sponsoring the study:**

**Names, degrees, and affiliations of the principal investigator and study coordinator (if applicable):**

**Principal Investigator:**

**Study Coordinator:** [OPTIONAL]

**1.1 Key Study Information**

You may be eligible to take part in a research study. This form contains information that will help you decide whether to join the study. All information in this form is important. Take time to carefully review this information. After you finish, you should talk to the researchers about the study and ask them any questions you have. You may also wish to talk to others such as your friends, family, or other doctors about your possible participation in this study. If you decide to take part in the study, you will be asked to sign this form. Before you do, be sure you understand what the study is about.

**2. PURPOSE OF THis STUDY**

**2.1 Study purpose:**

***Refer to the blue box version of the consent template for additional instructions and required language.***

**3. Who May Participate in the study**

Taking part in this study is completely **voluntary**. You do not have to participate if you don't want to. You may also leave the study at any time. If you leave the study before it is finished, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled.

***Refer to the blue box version of the consent template for additional instructions and required language.***

**3.1 Who can take part in this study?**

**3.2 How many people are expected to take part in this study?**

**4. information about study participation**

***Refer to the blue box version of the consent template for additional instructions and required language.***

**4.1 What will happen to me in this study?**

**4.2 How much of my time will be needed to take part in this study?**

**4.3 When will my participation in the study be over?**

**4.4 What will happen with my information and/or biospecimens used in this study?**

Your biospecimens and collected information may be shared with [PROVIDE SPONSOR NAME, OR DELETE THIS SENTENCE IF THERE IS NO SPONSOR].

With appropriate permissions, your biospecimens and collected information may also be shared with other researchers, here, around the world, and with companies.

Your identifiable private information or identifiable biospecimens may be stripped of identifiers and used for future research studies or distributed to another researcher for future research studies without additional informed consent.

**5. information about Study RISKS and benefits**

***Refer to the blue box version of the consent template for additional instructions and required language.***

**5.1 What risks will I face by taking part in the study? What will the researchers do to protect me against these risks?**

The known or expected risks are:

The researchers will try to minimize these risks by:

Additionally, there may be a risk of loss to confidentiality or privacy. See Section 9 of this document for more information on how the study team will protect your confidentiality and privacy.

As with any research study, there may be additional risks that are unknown or unexpected.

**5.2 What happens if I get hurt, become sick, or have other problems as a result of this research?**

The researchers have taken steps to minimize the risks of this study. Even so, you may still have problems or side effects, even when the researchers are careful to avoid them. Please tell the researchers listed in Section 10 about any injuries, side effects, or other problems that you have during this study. You should also tell your regular doctors**.**

**5.3 If I take part in this study, can I also participate in other studies?**

*Being in more than one research study at the same time, or even at different times, may increase the risks to you. It may also affect the results of the studies*. You should not take part in more than one study without approval from the researchers involved in each study.

**5.4 How could I benefit if I take part in this study? How could others benefit?**

You may not receive any personal benefits from being in this study. However, others may benefit from the knowledge gained from this study.

**5.5 Will the researchers tell me if they learn of new information that could change my willingness to stay in this study?**

Yes, the researchers will tell you if they learn of important new information that may change your willingness to stay in this study. If new information is provided to you after you have joined the study, it is possible that you may be asked to sign a new consent form that includes the new information.

**6. Alternatives to Participating in the study**

***Refer to the blue box version of the consent template for additional instructions and required language.***

**6.1 If I decide not to take part in this study, what other options do I have?**

**7. ENDING THE STUDY**

***Refer to the blue box version of the consent template for additional instructions and required language.***

**7.1 If I want to stop participating in the study, what should I do?**

You are free to leave the study at any time. If you leave the study before it is finished, there will be no penalty to you. You will not lose any benefits to which you may otherwise be entitled. If you choose to tell the researchers why you are leaving the study, your reasons for leaving may be kept as part of the study record. If you decide to leave the study before it is finished, please tell one of the persons listed in Section 10 “Contact Information”.

**7.2 Could there be any harm to me if I decide to leave the study before it is finished?**

**7.3 Could the researchers take me out of the study even if I want to continue to participate?**

Yes. There are many reasons why the researchers may need to end your participation in the study. Some examples are:

* The researcher believes that it is not in your best interest to stay in the study.
* You become ineligible to participate.
* Your condition changes and you need treatment that is not allowed while you are taking part in the study.
* You do not follow instructions from the researchers.
* The study is suspended or canceled.

**8. Financial Information**

***Refer to the blue box version of the consent template for additional instructions and required language.***

**8.1 Who will pay for the costs of the study? Will I or my health plan be billed for any costs of the study?**

The study will pay for research-related items or services that are provided only because you are in the study. If you are not sure what these are, see Section 4.1 above or ask the researchers for a list. If you get a bill you think is wrong, call the researcher’s telephone number listed in Section 10.1.

You or your health plan will pay for all the things you would have paid for even if you were not in the study, like:

* Health care given during the study as part of your regular care
* Items or services needed to give you study drugs or devices
* Monitoring for side effects or other problems
* Deductibles or co-pays for these items or services.

If you do not have a health plan, or if you think your health plan may not cover these costs during the study, please talk to the researchers listed in Section 10 below or call your health plan’s medical reviewer.

By signing this form, you do not give up your right to seek payment if you are harmed as a result of being in this study.

**8.2 Will I be paid or given anything for taking part in this study?**

**8.3 Who could profit or financially benefit from the study results?**

The company whose product is being studied:

The researchers conducting the study:

The University of Michigan:

Research can lead to new discoveries, such as new tests, drugs, or devices. Researchers, their organizations, and other entities, including companies, may potentially benefit from the use of the data or discoveries. You will not have rights to these discoveries or any proceeds from them.

**9. confidentiality of subject records and authorization to release your protected health information**

***Refer to the blue box version of the consent template for additional instructions and required language.***

The information below describes how the confidentiality of your research records will be protected in this study, and any sub-studies described in this document.

**9.1 How will the researchers protect my information?**

A description of this clinical trial will be available on <http://www.clinicaltrials.gov/>, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

**9.2 What protected health information (PHI) about me could be seen by the researchers or by other people? Why? Who might see it?**

Signing this form gives the researchers your permission to obtain, use, and share information about you for this study, and is required in order for you to take part in the study.

Medical information and billing records are protected by the privacy regulations of the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA). This type of information is called protected health information (PHI). PHI about you may be obtained from any hospital, doctor, and other health care provider involved in your care, including:

* Hospital/doctor's office records, including test results (X-rays, blood tests, urine tests, etc.)
* Mental health care records (except psychotherapy notes not kept with your medical records)
* Alcohol/substance abuse treatment records
* HIV/AIDS status
* Sexually transmitted disease and/or other communicable disease status
* Genetic counseling/genetic testing records
* Health plan/health insurance records
* All records relating to your condition, the treatment you have received, and your response to the treatment
* Billing information
* Demographic information
* Personal identifiers
* Other information

There are many reasons why information about you may be used or seen by the researchers or others during or after this study. Examples include:

* The researchers may need the information to make sure you can take part in the study.
* The researchers may need the information to check your test results or look for side effects.
* University, Food and Drug Administration (FDA) and/or other government officials, auditors, and/or the IRB may need the information to make sure that the study is done in a safe and proper manner.
* Study sponsors or funders, or safety monitors or committees, may need the information to:
	+ Make sure the study is done safely and properly
	+ Learn more about side effects
	+ Analyze the results of the study
* Insurance companies or other organizations may need the information in order to pay your medical bills or other costs of your participation in the study.
* The researchers may need to use the information to create a databank of information about your condition or its treatment.
* Information about your study participation may be included in your regular UMHS medical record.
* If you receive any payments for taking part in this study, the University of Michigan accounting department may need your name, address, Social Security number, payment amount, and related information for tax reporting purposes.
* Federal or State law may require the study team to give information to government agencies. For example, to prevent harm to you or others, or for public health reasons.

The results of this study could be published in an article, but would not include any information that would let others know who you are.

**9.3 What happens to information about me after the study is over or if I cancel my permission to use my PHI?**

As a rule, the researchers will not continue to use or disclose information about you, but will keep it secure until it is destroyed. Sometimes, it may be necessary for information about you to continue to be used or disclosed, even after you have canceled your permission or the study is over.

Examples of reasons for this include:

* To avoid losing study results that have already included your information
* To provide limited information for research, education, or other activities. (This information would not include your name, social security number, or anything else that could let others know who you are.)
* To help University and government officials make sure that the study was conducted properly

As long as your information is kept within the University of Michigan Health System, it is protected by the Health System’s privacy policies. For more information about these policies, ask for a copy of the University of Michigan “Notice of Privacy Practices”. This information is also available on the web at [http://www.uofmhealth.org/patient+and+visitor+guide/hipaa](http://www.uofmhealth.org/patient%2Band%2Bvisitor%2Bguide/hipaa). Note that once your information has been shared with others as described under Question 9.2, it may no longer be protected by the privacy regulations of the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA).

**9.4 When does my permission to use my PHI expire?**

Your permission expires at the end of the study, unless you cancel it sooner. You may cancel your permission at any time by writing to the researchers listed in Section 10 "Contact Information" (below). If you withdraw your permission, you may no longer be eligible to participate in this study.

**10. Contact Information**

***Refer to the blue box version of the consent template for additional instructions and required language.***

**10.1 Who can I contact about this study?**

Please contact the researchers listed below to:

* Obtain more information about the study
* Ask a question about the study procedures or treatments
* Talk about study-related costs to you or your health plan
* Report an illness, injury, or other problem (you may also need to tell your regular doctors)
* Leave the study before it is finished
* Express a concern about the study

Principal Investigator:
Mailing Address:
Telephone:

Study Coordinator:
Mailing Address:
Telephone:

**You may also express a question or concern about a study by contacting the Institutional Review Board listed below:**

University of Michigan Medical School Institutional Review Board (IRBMED)
2800 Plymouth Road
Building 520, Room 3214
Ann Arbor, MI 48109-2800
Telephone: 734-763-4768 (For International Studies, include the appropriate [calling codes](http://www.countrycodes.com/international-dialing-codes.php).)
Fax: 734-763-1234
e-mail: irbmed@umich.edu

If you are concerned about a possible violation of your privacy or concerned about a study you may contact the University of Michigan Health System Compliance Help Line at 1-866-990-0111.

*When you call or write about a concern, please provide as much information as possible, including the name of the researcher, the IRBMED number (at the top of this form), and details about the problem. This will help University officials to look into your concern. When reporting a concern, you do not have to give your name unless you want to.*

**11. record of Information provided**

***Refer to the blue box version of the consent template for additional instructions and required language.***

**11.1 What documents will be given to me?**

Your signature in the next section means that you have received copies of all of the following documents:

* This "Consent to be Part of a Research Study" document. (*Note: In addition to the copy you receive, copies of this document will be stored in a separate confidential research file and may be entered into your regular University of Michigan medical record.)*
* Other (specify):

**12. Signatures**

***Refer to the blue box version of the consent template for additional instructions and required language.***

**Sig-A**

**Consent/Assent to Participate in the Research Study**

I understand the information printed on this form. I have discussed this study, its risks and potential benefits, and my other choices with [NAME OF STUDY TEAM MEMBER OBTAINING CONSENT] \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_. My questions so far have been answered. I understand that if I have more questions or concerns about the study or my participation as a research subject, I may contact one of the people listed in Section 10 (above). I understand that I will receive a copy of this form at the time I sign it and later upon request. I understand that if my ability to consent or assent for myself changes, either I or my legal representative may be asked to re-consent prior to my continued participation in this study.

Print Legal Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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Date of Signature (mm/dd/yy): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Sig-B**

**Consent/Assent to video/audio recording/photography solely for purposes of this research**

This study involves video and/or audio recording and/or photography. If you do not agree to be recorded, you [CAN STILL/CANNOT] take part in the study.

\_\_\_\_\_ Yes, I agree to be video/audio recorded/photographed.

\_\_\_\_\_ No, I do not agree to be video/audio recorded/photographed.

Print Legal Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date of Signature (mm/dd/yy): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Sig-C**

**Consent/Assent for Participating in an Optional Sub-Study**

This project involves optional participation in a sub-study. I understand that it is my choice whether or not to take part in the sub-study. I understand that if my ability to consent or assent for myself changes, either I or my legal representative may be asked to re-consent prior to my continued participation in this study.

\_\_\_\_\_ Yes, I agree to take part in the optional sub-study.

\_\_\_\_\_ No, I do not agree to take part in the optional sub-study.

Print Legal Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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Date of Signature (mm/dd/yy): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Sig-D**

**Consent/Assent to Collect for Unspecified Future Research**

This project involves the option to allow the study team to keep your identifiable specimens/data for use in future research. I understand that it is my choice whether or not to allow future use of my specimens. I understand that if my ability to consent or assent for myself changes, either I or my legal representative may be asked to re-consent prior to my continued participation in this study.

\_\_\_\_\_ Yes, I agree to let the study team keep my specimens for future research.

\_\_\_\_\_ No, I do not agree to let the study team keep my specimens for future research.

Print Legal Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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Date of Signature (mm/dd/yy): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Sig-E**

**Legally Authorized Representative or Parent Permission**

Subject Name:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Parent/Legally Authorized Representative:**

Printed Legal Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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Date of Signature (mm/dd/yy): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Relationship to subject: Parent Spouse Child Sibling Legal guardian Other

*If “Other,” explain: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*

Reason subject is unable to consent: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

*If this consent is for a child who is a ward of the state (for example, a foster child), please tell the study team immediately. The researchers may need to contact IRBMED.*

**Sig-F**

**Second Parent Permission**

Printed Legal Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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Date of Signature (mm/dd/yy): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

*Reason second parent permission was not collected:*

 Parent is deceased Parent is unknown

 Parent is incompetent Only one parent has legal responsibility for care and custody

 Prospect of direct benefit solely to the fetus and pregnancy resulted from rape or incest

 Parent is not reasonably available\*; explain: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

*\* Note: “Not reasonably available” means the other parent is not able to be contacted by phone, mail, email, or fax, or his or her whereabouts are unknown. It does not mean that the other parent is at work or home, or that he or she lives in another city, state, or country.*

**Sig-G**

**Principal Investigator or Designee**

I have provided this participant and/or his/her legally authorized representative(s) with information about this study that I believe to be accurate and complete. The participant and/or his/her legally authorized representative(s) indicated that he or she understands the nature of the study, including risks and benefits of participating.

Printed Legal Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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Date of Signature (mm/dd/yy): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Sig-H**

**Witness**

I observed the above subject (or his/her legally authorized representative, if applicable) sign this consent document.

Printed Legal Name:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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Date of Signature (mm/dd/yy): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_